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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,590	01/08/2001	Stewart Russell Jurgensen	P-4993	5633

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/28/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,590

Applicant(s)

JURGENSEN ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-18) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Group II (Claims 19-30) and Group III (Claims 31-36) are directed to the same method for harvesting components from a sample as that of Group I. This is found persuasive because upon reevaluation of the restriction made of record. The method steps of Groups II and III does not distinguish them from Group I as independent and distinct invention. But rather they are an added limitation. Therefore Groups II and III are rejoined with Group I.
2. Claims 1-36 are treated on the merit in this Office Action.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "64" and "52" have both been used to designate microbeads. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "66, 68, 70, 72, 74" (pg. 18, lines 28-29 to pg. 19, lines 1-4) and "62, 64, 34, 32" (pg. 19, lines 1-14) of figure 5. A proposed drawing correction or corrected drawings are required in reply to the Office action to

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avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “6” of figure 3 and “5” of figure 4. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 5, 7-12, 14, 18, 21, 23, 32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is incomplete because it lacks a correlation step.

b) The phrase “axial through passage” of Claim 5 is vague and indefinite because it is unclear of what an axial through passage of the float is. Is the passage part of the tube or the float?

- c) The phrase “having a through passage” of Claims 19 and 31 is vague and indefinite because it is unclear of who has the through passage. Is the passage part of the tube or the float?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-7, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (US Patent 5,635,362).

Levine teaches the device and method for the analyses of blood sample for the presence or absence of a target analyte or analytes that are caused to settle in a predetermined location in a transparent tube (col. 1, lines 9-18). The assay method disclosed comprised of adding the sample to the tube so as to allow the density-marker/binding material capture body or bodies to incubate and intermix with the sample sufficiently to cause any target analytes present in the sample to couple with and be captured by their complementary partners on the density-markers before centrifugation (col. 3, lines 35-54). The tube is a transparent tube with a float/insert (col. 6, lines 10-17; fig. 1 and 2). The float/inserts is cylindrical and movable and it has a specific gravity such that it would sink through the red cell layer in the centrifuged blood sample or come to rest in an area where the density-marker/binding material capture body or bodies also come to rest (col. 2, lines 46-52). The blood sample is centrifuged in the tube and the density-marker/binding material capture body or bodies with different specific gravity will form bands that settle into the restricted space between the float/insert in the tube (col. 2, lines 38-67; col. 3, lines 1-12). The density-marker/binding material captures body or bodies are beads that are

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coupled with a capture binding material such as antibodies (col. 3, lines 13-34). The target analyte of interest are lymphocyte blood cells (white blood cells) or hematopoietic progenitor blood cells (stem cell or fetal cell), which can be found in bone marrow, peripheral blood or cord blood (col. 9, lines 51-53; col. 10, lines 51-57). The method of Levine anticipated the claimed method.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 2-3, 19-20, 22, 24-27, 30, 31, 33-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,635,362) in view of Levine et al. (US Patent 5,393,674).

The method of Levine (US Patent 5,635,362) is disclosed above and is now refer to as Levine #1.

Levine #1 differs from the instant invention in failing to include in the method step of removing the target component and the float includes ribs.

Levine (US Patent 5,393,674), which is now refer to as Levine #2, teaches a device and method for centrifuging blood into its constituent layers similar to the instant invention and that of Levine #1 (col. 1, lines 7-14; fig. 1 and fig. 4). The method of Levine #2 comprise of centrifuging the blood sample in a glass tube, which contains a float (col. 2, lines 61-68 to col. 3, lines 1-12). The float is formed with a core portion which has a through bore (channel) (ref. #7 of fig. 1), and an annular sleeve portion (ribs) (ref # 11 of fig. 1) that expands and contracts responsive to the magnitude of dynamic forces imposed on the float during performance of the sample centrifugation (col. 2, lines 15-19; col. 4, lines 6-14). The cells and components of the buffy coat layer are expanded linearly in the narrow bore channel in the float and thus can be easily harvested (col. 3, lines 13-15). The method includes harvesting the target cells from the float bore (ref. #7 of fig. 5) with a needle (col. 4, lines 55-57; fig. 5).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Levine #1 by incorporating the method step of removing the target component as taught by Levine #2 because it would provide the advantage of performing multiple methods such as cell concentration, assay, and harvesting in a unitary sealed tube (Levine #2: col. 1, lines 41-57). This would also reduce exposure of contaminated blood to the technician and the disposal of contaminated blood would be in a stable, inert environment. The ribs of the float would provide a ten fold expansion of the white cell and platelet layers when performing the cell harvesting with the tube-float combination (Levine #2: col. 2, lines 50-60). Therefore, one would have had reasonable expectation of success of incorporating the method step of removing the target component into the method of Levine #1 because both Levine #1 and Levine #2 teaches the method of cell separation.

13. Claims 8-12, 14, 18, 21, 23, 28-29, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (US Patent 5,635,362) in view of Van Vlasselaer (US Patent 5,474,687).

The method of Levine is disclosed above.

Levine differs from the instant invention in failing to specifically disclosed the density, size and type of the beads.

Van Vlasselaer teaches a method of density-adjusted cell sorting which uses cell type-specific binding agents such as antibodies and lectins linked to carrier particles (beads) to impart a different density to cell populations in blood allowing the cells to be separated during centrifugation (col. 1, lines 13-19). The carrier particles (beads) include polystyrene latex and

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organic polymer such as polyvinyl compounds (col. 11, lines 45-53). The particle size of 0.1 to 5.0 micron (col. 11, lines 45-67 to col. 12, lines 1-3). The density is adjusted 1.06 g/ml in order to ensure reproducibility and accuracy of the cell separation (col. 13, lines 22-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the density beads of Levine with those density beads of Van Vlasselaer. One of ordinary skill would be motivated because both Levine and Van Vlasselaer teaches methods of providing accurate and reproducible cell separation layers. Levine teaches for cell separation that different density beads are needed to produce different bands in the tube to permit rapid screening and identification (Levine: col. 4 lines 11-25). Further, Van Vlasselaer disclosed that there is a number of commercially available beads can be use in the method of cell separation (Van Vlasselaer: col. 11, lines 45-53). The choice of one particular type of beads is dependent on the availability and accessibility. Therefore, one would have known to substitute the density beads of Levine with density beads of Van Vlasselaer to separate the desired cells. One would have had reasonable expectation of success using the beads of Van Vlasselaer with the method of Levine because both use the similar method to achieve cell separation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

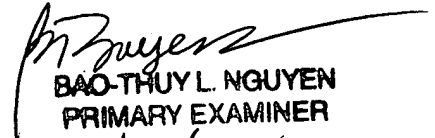
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
August 26, 2002


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
8/26/02